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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,087	12/06/2004	Christian von Falkenhausen	RO0937US (#90568)	1143
7590 D Peter Hochberg Company 6th Floor 1940 East 6th Street Cleveland, OH 44114			EXAMINER SUTTON, DARRYL C	
			ART UNIT	PAPER NUMBER
			1612	
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			07/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/517,087

Applicant(s)

FALKENHAUSEN ET AL.

Examiner

DARRYL C. SUTTON

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 and 24-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 19-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/08)
- Paper No(s)/Mail Date 12/06/2004.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application.
- 6) ☐ Other: ____.

DETAILED ACTION

Applicant's election with traverse of the Requirement for Restriction in the reply filed on 3/07/2008 is acknowledged. The traversal is on the ground(s) that the Groups as assigned in the Restriction requirement are not patently distinct. The applicant's argument concerning Groups I and II is persuasive, but there was no argument concerning a common technical feature between either of those Groups (I or II) and Group III. Therefore, because the applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election of species of (a) oxygen-containing compound, hydrogen peroxide (b) antioxidant, tocopherols, (c) layer, mono-layer (d) polymer, cellulose ether (e) additive, permeation-enhancing substance, and (f) active substance, nicotine, and corresponding claims 1-12 and 19-23 in the reply filed on 3/07/2008 is acknowledged. Claims 13-18 and 24-29 are withdrawn from further consideration as being drawn to non-elected subject matter.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, courts have indicated what does not constitute same. See, e.g., In re Gostelli, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two compounds within a subgenus did not adequately describe such subgenus.

As outlined in Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997), a description of a genus can comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under Section 112, Para. 1, by showing the enablement of a representative number of species within the genus. Mere indistinct terms (here the term "oxygen-containing compounds"), however, may not suffice to meet the written description requirement.

The instant specification does not describe specific "oxygen-containing compounds", other than peroxides. That listing of a single species is far narrower in scope than the broad genus "oxygen-containing compounds", and claim 3 fails to recite any structural features common to the members of that genus which would constitute a substantial portion of the same. Accordingly, the term "oxygen-containing compounds" as used currently by instant claim 3 is deemed so indistinct that it fails to reasonably convey to one skilled in the art that applicant was in possession of a representative number of species within that genus.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a

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question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "comprises both molecular oxygen and oxygen-containing compounds", and the claim also recites "includes peroxides...." which is the narrower statement of the range/limitation.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially free" in claim 3 is a relative term which renders the claim indefinite. The term "substantially free" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 1-12, 14 and 19-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "film-like" in claim 1 is a relative term which renders the claim indefinite. The term "film-like" is not defined by the claim, the specification does not provide a

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standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Deadman (GB 1,061,557).

Deadman teaches a coated or impregnated film (column 1, lines 9-10). The invention consists in self-supporting films of gelatin or rice paper coated or impregnated with a drug for oral administration (column 1, lines 29-34).

The prior art anticipates the instant invention insofar as it discloses a film impregnated with an active substance for oral administration, i.e. in the oral cavity. Since the film is comprised of natural ingredients, it does not contain any free oxygen or peroxides and will inherently have a peroxide number lower than 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theobald et al. (WIPO 01/080837, U.S. Patent Pub. 2003/0049308 provided for translation purposes) in view of Muller (WIPO 01/39753, U.S. Patent 6,699,498 provided for translation purposes).

Theobald et al. teach a transdermal or transmucosal administration form comprising nicotine (Abstract, paragraphs [0001] and [0012]). In its simplest embodiment, the active substance reservoir is a single-layer polymer matrix; the matrix may further comprise auxiliaries and additives, especially additives which promote skin

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permeation, i.e. permeation enhancers (paragraphs [0023] and [0025]). A transmucosal form of the invention comprising nicotine is preferably designed as a flat, film-like carrier and is provided with mucoadhesive properties, which are brought about through the addition of carboxymethylcellulose, hydroxypropylcellulose, ethylcellulose or propylcellulose [paragraph [0031]].

Theobald et al. does not teach the limitation of "peroxide number" or that the invention is further comprised of antioxidants.

Muller teaches a transdermal therapeutic system (TTS) in which the formation of oxidative degradation products of the oxidation sensitive active substance present is reduced during storage; this objective is achieved by using only those formulations constituents which are substantially free of hydroperoxides (column 6, lines 7-15). TTS may be differentiated into matrix systems and reservoir systems, where the active ingredient is particularly sensitive to reactions which lead to an impairment of stability (column 1, lines 5-25). The stability of the active substance and of auxiliaries may be put at risk by reaction with active oxygen. Raw materials used to produce TTS may to a considerable extent comprise active oxygen in the form of hydroperoxides (column 1, lines 57-60, column 2, lines 48-57). Free-radical scavengers, antioxidants, such as tocopherol and its derivatives remove or inactivate free radicals; and interfere with autoxidation reactions, i.e. degradation, reduction in stability (column 2, lines 33-42). Additional improvement of stability is achieved by the addition of antioxidants (column 7, lines 10-13). The TTS of the invention have a peroxide number of not more than 5 (column 6, lines 15-19, column 7, lines 14-17). They include as building blocks of a

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single-layer matrix, polymers, such as polyacrylates, polymethacrylates, and PVP; and functional additives or auxiliaries, such as permeation enhancers (column 6, lines 24-44). If the constituents are loaded with considerable amounts of hydroperoxides, these substances need to be substantially freed from hydroperoxides prior to use by reducing them in strong reducing substances, such as sodium and sodium hydrogen sulfite (column 6, lines 44-67, column 7, lines 32-36). Following this treatment, the materials are virtually free from peroxides (column 7, lines 8-10).

Muller does not teach a film-like preparation comprised of nicotine.

It is generally prima facie obvious to select a compound based on its suitability for its intended use. SEE MPEP 2144.07. Therefore it would have been obvious to modify the invention of Theobald et al. to use the tocopherol of Muller motivated by the desire to improve the stability as taught by Muller. It would have also been obvious to modify the constituents of the invention of Theobald et al. by reducing them with the sodium hydrogen sulfite of Muller prior to use, motivated by the desire to lower the peroxide number to 5 by removing peroxides which improves the stability as taught by Muller.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See MPEP 2144.05, II. Optimization of Ranges. Therefore, the optimum or workable amount of antioxidant used in the instant invention is ascertained through routine experimentation.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 8:30AM- 6:00PM and on Fr from 7:30AM-4:00PM EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/

Examiner, Art Unit 1612

/Gollamudi S Kishore, Ph.D/

Primary Examiner, Art Unit 1612